UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------x

LORI CANALE, individually and on behalf of all others similarly situated,

Plaintiff,

No. 16-CV-3308 (CS)

– against –

OPINION & ORDER

COLGATE-PALMOLIVE CO.,

Defendant.

----------x

Appearances:

Scott A. Bursor
Joseph I. Marchese
Frederick J. Klorczyk III
Philip L. Fraietta
Bursor & Fisher, P.A.
New York, New York
Counsel for Plaintiff

Nathaniel J. Kritzer
Richard W. Nicholson
Kirkland & Ellis LLP
New York, New York
Robyn E. Bladow
Kirkland & Ellis LLP
Los Angeles, California
Counsel for Defendant

Seibel, J.

Plaintiff Lori Canale brings this putative class action arising out of allegedly misleading labeling on whitening toothpastes sold by Defendant Colgate-Palmolive Co. Before the Court is Defendant's motion to dismiss or stay the case. (Doc. 26.) For the reasons stated below, the motion is GRANTED in part and DENIED in part.

I. BACKGROUND

Defendant sells Colgate Optic White[1] and Colgate Optic White Platinum[2] toothpastes (together the "Optic White products") at a premium price to "capitalize on consumer demand for whitening toothpaste." (Compl. ¶¶ 1, 2.) Since October 2013, Defendant has represented that Colgate Optic White toothpaste "Goes Beyond Surface Stain Removal to Deeply Whiten" teeth. (*Id.* ¶ 2.) Since February 2014, Defendant has represented that Colgate Optic White Platinum toothpaste "Deeply Whitens More Than 3 Shades." (*Id.*) Both toothpastes contain the same supposedly whitening ingredient – 1% hydrogen peroxide. (*Id.*) Plaintiff alleges, however, that 1% hydrogen peroxide does not in fact "go beyond surface stain removal" or "deeply whiten teeth because there is not enough hydrogen peroxide in toothpaste, and the peroxide is not in contact with teeth for long enough." (*Id.*) Plaintiff bought Colgate Optic White based on the claims Defendant made about Colgate Optic White's whitening capabilities, and was "deceived into believing that Optic White goes beyond surface stains to deeply whiten teeth." (*Id.* ¶¶ 3, 4.) Plaintiff was injured because the toothpaste she purchased did not deeply whiten her teeth or whiten "intrinsic stains." (*Id.* ¶ 4.)

A. Defendant's Marketing of Optic White Products

Plaintiff complains of both the toothpastes' packaging and two television commercials Defendant used to market its products. First, the Optic White labels state that the toothpaste "Goes Beyond Surface Stain Removal To Deeply Whiten Teeth," that it "Deeply Whiten[s]," and that "Optic White toothpaste is clinically proven to whiten teeth with peroxide [and] goes

[1] "Optic White" toothpastes include Colgate Optic White Sparkling White, Colgate Optic White Icy Fresh, Colgate Optic White Enamel White, Colgate Optic White Sparkling Mint, and Colgate Optic White Mild Mint. (Doc. 1 ("Compl.") ¶ 10.)

[2] "Optic White Platinum" toothpastes include Colgate Optic White Platinum White & Radiant and Colgate Optic White Platinum Lasting White, both of which are alleged to have been formerly known as "Optic White Platinum Whiten & Protect." (*Id.* ¶ 11.)

beyond surface stains unlike ordinary toothpastes." (*Id.* ¶ 12.) The Optic White Platinum labels state that the toothpaste "Deeply Whitens More Than 3 Shades." (*Id.* ¶ 11.)

Second, Plaintiff complains of television commercials advertising the toothpastes. One of those commercials depicts a shell "made of calcium that can absorb stains like teeth" that is dipped in red wine for 10 hours. (*Id.* ¶ 13.) The commercial illustrates the toothpaste's "supposed deeply whitening capabilities" by comparing one side of the shell – which was brushed with regular whitening toothpaste and remains dark – with the other side – which was brushed with Optic White toothpaste and appears white. (*Id.* ¶ 14.) Beneath this shell depiction, text appears stating, "Colgate Optic White can penetrate to work below the tooth's surface." (*Id.*) Another commercial zooms in on several teeth and depicts "sparkly Optic White particles" whitening the teeth, while stating, "Unlike the leading whitening toothpaste, Colgate Optic White toothpaste goes beyond surface stains to deeply whiten teeth." (*Id.* ¶¶ 16, 17.)

According to Plaintiff, "toothpastes cannot go beyond surface stains to deeply whiten teeth because peroxide in toothpaste does not function as a whitening agent on intrinsic stains." (*Id.* ¶ 12.) Optic White toothpastes thus only reach surface stains by abrading the surface of the teeth. (*Id.*) Plaintiff alleges, citing various studies and scholarly articles, that "dentists agree that peroxide in toothpaste does not work on intrinsic stains because the amount of peroxide in toothpaste is too small and gets rinsed away before it can deeply whiten teeth." (*Id.* ¶ 19; *see id.* ¶¶ 19-32.)

In 2012, the National Advertising Division of the Council of Better Business Bureaus ("NAD") cautioned Defendant to avoid attributing whitening improvement from Optic White toothpastes to its peroxide ingredient. (*Id.* ¶ 33.) NAD recommended that Defendant discontinue any claims suggesting that hydrogen peroxide in toothpaste deeply whitens or

whitens below surface stains, as Defendant "did not have sufficient evidence to support th[at] message." (*Id.*) Defendant did not change its advertising claims. (*Id.*)

In 2014, NAD conducted a compliance inquiry relating to the following claims on Optic White's packaging: "Goes Beyond Surface Stain Removal to Deeply Whiten," "This Unique Formula is Clinically Proven to Whiten Teeth With Peroxide," and "Goes Beyond Surface Stains Unlike Ordinary Toothpastes." (*Id.* ¶ 34.) In response to this inquiry, Defendant claimed that it had "reformulated" Optic White and that new evidence supported its claims about the toothpaste's intrinsic whitening capabilities. (*Id.* ¶ 35.) NAD disagreed because any reformulations did not change the amount of peroxide in the toothpaste and did not address "Optic White's ability to provide whitening benefits below the tooth surface." (*Id.*) NAD concluded that Defendant's 2014 claims were "not markedly different from the claim [NAD] recommended be discontinued in 2012," and thus that Defendant should remove the word "deeper" from its advertising claims and "avoid any implication that the Optic White product intrinsically whitens teeth." (*Id.*) Defendant again did not accept NAD's recommendation. (*Id.*) On July 10, 2014, NAD referred the matter to the Federal Trade Commission ("FTC"). (Doc. 28 Exs. 1-2.) The FTC's investigation is ongoing. (*See id.* Exs. 3-7; Doc. 39 Exs. 9-17.)

Plaintiff filed her putative class action on May 3, 2016. She brings claims for breach of express warranty individually and on behalf of all persons in the United States who purchased Optic White on or after October 1, 2013, or who purchased Optic White Platinum on or after February 1, 2014. (*Id.* ¶ 5.)[3] She also brings claims for violations of Sections 349 and 350 of the New York General Business Law ("GBL") individually and on behalf of all purchasers of Optic

[3] Plaintiff's putative breach of warranty class excludes purchasers in California, Delaware, the District of Columbia, Kansas, Missouri, New Jersey, Ohio, Utah, Virginia, and West Virginia, (Compl. ¶ 5), whose claims are being asserted in *Dean v. Colgate-Palmolive Co.*, No. 15-CV-107 (C.D. Cal.), (*id.* ¶¶ 36-39).

White products in New York. (*Id.*) Section 349 makes unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law § 349(a). Section 350 makes unlawful "[f]alse advertising in the conduct of any business, trade or commerce." *Id.* § 350. The basis for all three claims is Defendant's claim that its Optic White products "go beyond surface stains to deeply whiten teeth," which Plaintiff alleges is false and misleading. (Compl. ¶ 53; *see id.* ¶¶ 59, 68.)

II. DISCUSSION

A. Legal Standard

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (alteration, citations, and internal quotation marks omitted). While Federal Rule of Civil Procedure 8 "marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, . . . it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 556 U.S. at 678-79.

In considering whether a complaint states a claim upon which relief can be granted, the court "begin[s] by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth," and then determines whether the remaining well-pleaded

factual allegations, accepted as true, "plausibly give rise to an entitlement to relief." *Id.* at 679. Deciding whether a complaint states a plausible claim for relief is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not 'shown' – 'that the pleader is entitled to relief.'" *Id.* (alteration omitted) (quoting Fed. R. Civ. P. 8(a)(2)).

B. Preemption

Defendant first argues that Plaintiff's claims under state law are expressly preempted by the Food Drug & Cosmetics Act ("FDCA"), and should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6).

Defendant argues that as both a drug and a cosmetic, its Optic White products are subject to "broad" regulation by the Food and Drug Administration ("FDA"). (Doc. 27 ("D's Mem."), at 3-4.) Where a product qualifies as both a drug and a cosmetic under the FDCA, it is "subject to the stricter requirements applicable to drugs." *Elkind v. Revlon Consumer Prods. Corp.*, No. 14-CV-2484, 2015 WL 2344134, at *7 (E.D.N.Y. May 14, 2015) (citing *United States v. Article . . . Consisting of 216 Cartoned Bottles, More or Less, Sudden Change*, 409 F.2d 734, 739 (2d Cir. 1969)); *see Estee Lauder, Inc. v. U.S. Food & Drug Admin.*, 727 F. Supp. 1, 2 (D.D.C. 1989) ("If a product is both [a cosmetic and a drug], it must comply with the stricter requirements applicable to drugs."). In general, manufacturers are prohibited from selling drugs with "false or misleading" labeling. *See* 21 U.S.C. § 331(a) (prohibiting introduction into interstate commerce of misbranded drugs); *id.* § 352(a)(1) (drug is misbranded "[i]f its labeling is false or misleading in any particular"). Further, "[u]nder the [FDCA], a new drug may not enter interstate commerce unless FDA determines that it is generally recognized as safe and

effective . . . for the particular use described in its product labeling." *NRDC, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013) (citing 21 U.S.C. §§ 321(p)(1), 355(a)). In general, the FDA must approve new drugs individually. *Id.* In some cases, however, the FDA will issue a "monograph," which "sets out the FDA-approved active ingredients for a given therapeutic class of [over-the-counter] drugs and provides the conditions under which each active ingredient is [generally recognized as safe and effective]." *Id.* Where the FDA has issued an applicable monograph, the manufacturer may bypass the individual approval process by marketing its product according to the specific conditions laid out in the monograph. *See id.*

"Under the Supremacy Clause, Congress has the power to pre-empt state law expressly." *Hillman v. Maretta*, 133 S. Ct. 1943, 1949 (2013). "Express preemption is present when Congress's intent to preempt state law is explicitly stated in the statute's language." *In re PepsiCo, Inc., Bottled Water Mktg. & Sales Practices Litig.*, 588 F. Supp. 2d 527, 530 (S.D.N.Y. 2008) (internal quotation marks omitted).

Defendant contends that two provisions of the FDCA expressly preempt Plaintiff's state law claims: 21 U.S.C. §§ 379r, 379s. The FDCA explicitly says that states may not "establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this chapter." *Id.* § 379s(a). Similar language forbids non-identical state requirements for over-the-counter ("OTC") drugs. *See id.* § 379r(a);[4] *Bimont v. Unilever U.S., Inc.*, No. 14-CV-7749, 2015 WL 5256988, at *2 (S.D.N.Y. Sept. 9,

[4] Section 379r(a) provides that

> no State or political subdivision of a State may establish or continue in effect any requirement – (1) that relates to the regulation of [an OTC drug]; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

2015). I agree with Defendant that Congress expressly intended these two provisions to preempt state law labeling or packaging requirements that are not identical to FDA requirements. *See Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 374-75 (S.D.N.Y. 2014) (section 379r expressly preempts certain state law claims).[5]

Plaintiff argues that the starting point for the preemption analysis is "the assumption that the historic police powers of the States [a]re not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (internal quotation marks omitted). But Defendant correctly points out that where, as here, Congress has expressly manifested its intent to preempt state law, no presumption against preemption arises. *See Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016). Rather, courts "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *Chamber of Commerce of the U.S. v. Whiting*, 563 U.S. 582, 594 (2011) (internal quotation marks omitted). Thus the question is whether any of Plaintiff's claims seek to impose requirements that are "not identical with" an applicable federal requirement.

The FDCA prohibits the "false or misleading" labeling of drugs and cosmetics. *See* 21 U.S.C. §§ 331(a), 352(a)(1), 362(a). If this were the only federal requirement related to Optic White and Optic White Platinum, Plaintiff's claims would not be expressly preempted because she argues that Defendant's representations regarding deep whitening are false and misleading, and therefore seeks to impose a requirement identical to that under federal law: that Defendant

[5] Oddly, despite Defendant explicitly arguing for express preemption, (*see, e.g.*, D's Mem. 7), Plaintiff addresses only implied preemption. While express preemption arises where Congress has expressly manifested its intent to preempt state law, "[i]mplied preemption arises when, in the absence of explicit statutory language, Congress intended the Federal Government to occupy a field exclusively, or when state law actually conflicts with federal law." *Air Transp. Ass'n of Am. v. Cuomo*, 520 F.3d 218, 220 (2d Cir. 2008) (omission, alteration, and internal quotation marks omitted). Because Defendant does not argue that Plaintiff's claims are impliedly preempted, I need only address express preemption.

not label or package its products in a false or misleading way. *See Reid v. GMC Skin Care USA Inc.*, No. 15-CV-277, 2016 WL 403497, at *10 (N.D.N.Y. Jan. 15, 2016) ("Plaintiffs' claims, if proven to be true, would simply require Defendant to truthfully state the efficacy of its products or not sell its products; such relief would not impose a state requirement that is different from or in addition to, or that is otherwise not identical with that of the FDCA.") (alterations omitted).[6] But if there are other relevant federal requirements governing Defendant's products, they must be compared to the requirement Plaintiff seeks to impose via state law.

Where federal law specifically regulates the subject matter of a plaintiff's state law claims, and those claims seek to impose requirements not identical to federal requirements, those state law claims are preempted. *See Bimont*, 2015 WL 5256988, at *4-5 (while both state and federal law generally forbid "'misleading' packaging of dr[u]gs and cosmetics," proper inquiry is whether Congress and/or FDA has addressed specific subject matter of plaintiff's claims, *i.e.*, slack-fill in drug and cosmetics packaging); *In re PepsiCo, Inc.*, 588 F. Supp. 2d at 538 ("Where federal requirements address the subject matter that is being challenged through state law claims, such state law claims are preempted to the extent they do not impose identical requirements."); *id.* at 532 (state law fraudulent misrepresentation claims based on source of bottled water are not

[6] The court in *Elkind* arrived at the same conclusion but for a different reason:

> If this Court ultimately concludes that the challenged conduct is misleading under New York or California law, it might announce an additional labeling requirement on non-prescription drugs, but such a requirement would not *relate to* the FDCA's regulation of non-prescription drug labels, and such a requirement would therefore fall beyond the scope of the FDCA's province.

2015 WL 2344134, at *8. The court, discussing §§ 352 and 379r, reasoned that because the FDA "does not endeavor to regulate . . . whether certain phrases on the branding of non-prescription drugs are misleading," complaints about misleading labeling do not "relate to the FDCA's regulation of non-prescription drug labels." *Id.* at *7-8. But the plain text of § 379r preempts any non-identical state law requirement "that relates to the regulation of a[n] OTC drug." 21 U.S.C. § 379r(a)(1). A state law claim premised on false or misleading labeling necessarily "relates to" the FDCA's prohibition of false and misleading labeling. Such claims may not be preempted by § 379r, but that is because they impose requirements identical to federal law, not because they are outside the scope of the FDCA.

expressly preempted if they "are 'identical' to those imposed by the standard of identity for purified drinking water"); *cf. Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 425-26 (7th Cir. 2011) (to determine whether plaintiff's consumer protection claims based on representations about a snack bar's dietary fiber were preempted, court must examine "what requirements the federal law imposes on the labeling of dietary fiber"). Here, Defendant has identified several federal requirements that it contends specifically address the products at issue: (1) a final monograph for anticaries OTC drugs;[7] (2) previous, nonfinal versions of the same monograph; and (3) the denial of a citizen petition regarding the marketing and sale of peroxide-containing tooth-whitening products.[8] None of these requirements, however, address the whitening capabilities of hydrogen peroxide.

First, Defendant points to the monograph regulating "anticaries" OTC drugs as a federal requirement related to the Optic White products. That final monograph, which "establish[es] conditions under which OTC anticaries drug products . . . are generally recognized as safe and effective and not misbranded," provides that only three active ingredients meet its conditions: sodium fluoride, sodium monofluorophosphate, and stannous fluoride. *See* Anticaries Drug Products for Over-The-Counter Human Use; Final Monograph ("Anticaries Monograph"), 60 Fed. Reg. 52474, 52506 (Oct. 6, 1995) (codified at 21 C.F.R. pt. 355). "All other ingredients

[7] "Anticaries" drugs are those that "aid[] in the prevention and prophylactic treatment of dental cavities" or decay. 21 C.F.R. § 355.3(c).

[8] Defendant also points to FDA warning letters sent in 1991 to other manufacturers of peroxide-containing products that the FDA contended were marketed as drugs without FDA approval. (D's Mem. 4.) But Defendant merely cites the text of the FDA's denial of a citizen petition for the existence of such warning letters, and has not provided those warning letters to the Court. Even if it had, the letters could not be considered on a motion to dismiss under Rule 12(b)(6) unless they were publicly available, *see Byrd v. City of N.Y.*, No. 04-CV-1396, 2005 WL 1349876, at *1 (2d Cir. June 8, 2005) ("[M]aterial that is a matter of public record may be considered in a motion to dismiss."), or integral to the Complaint, *see Weiss v. Inc. Vill. of Sag Harbor*, 762 F. Supp. 2d 560, 567 (E.D.N.Y. 2011) (on 12(b)(6) motion, courts may consider "documents 'integral' to the complaint and relied upon in it, even if not attached or incorporated by reference"). In any event, the letters apparently did not address the products' whitening capability, and the FDA never issued a determination. (Doc. 28 Ex. 8, at 1-2.)

considered in [that] rulemaking have been determined to be nonmonograph conditions." *Id.* During the rulemaking, the FDA considered only one comment regarding a combination drug product containing 0.05% sodium fluoride and 1.5% hydrogen peroxide, which the commenter contended provided "concurrent therapy as an oral cleanser and anticaries agent for orthodontic patients." *Id.* at 52492. There is nothing in the monograph regarding whitening toothpastes or products. The monograph simply permits the sale, without a new drug application, of products the active ingredient of which is one of the three listed compounds, and it provides that the product is not misbranded if it contains the claims regarding decay prevention set forth in the monograph. It does not purport to address the issue raised by Plaintiff's claims here, or otherwise immunize any other representation made by the products' manufacturer. *See Dean*, 2015 WL 3999313, at *10 ("[T]he monograph in question does not refer to whitening toothpaste at all; it concerns over-the-counter anti-cavity drug products – which may be used in toothpastes – and when such products can be recognized (and labeled) as safe and effective.").

Second, Defendant argues that "the FDA specifically addressed the whitening effects of toothpastes" in a previous, nonfinal version of the Anticaries Monograph. (D's Mem. 4.) The tentative final monograph to which Defendant cites, however, discusses whether a warning is appropriate regarding temporary surface teeth staining caused by products containing stannous fluoride. *See* Anticaries Drug Products for Over-The-Counter Human Use; Tentative Final Monograph ("Tentative Final Monograph"), 50 Fed. Reg. 39854, 39865-66 (Sept. 30, 1985). It is concerned with stains occasioned by stannous fluoride, not stains ostensibly ameliorated by hydrogen peroxide. It does not include any discussion of hydrogen peroxide, much less a discussion of the "whitening effects of toothpastes" as Defendant claims.

Third, Defendant points to the FDA's denial of a citizen petition filed by the American Dental Association ("ADA") – which was apparently concerned about individuals using teeth-whitening products without consulting a dentist – requesting that peroxide-containing tooth whiteners be subjected to regulatory classification. *See* Citizen Petition Denial, Dkt. No. FDA-2009-P-0566 (Apr. 22, 2014), https://www.regulations.gov/document?D=FDA-2009-P-0566-0005.[9] In that decision, the FDA acknowledged peroxide-containing whitening products' classification as cosmetics, *id.* at 3, but declined the ADA's invitation to treat those products as drugs as well, *id.* at 4-5. The FDA explained that group treatment of peroxide-containing teeth whiteners was inappropriate because of the different means by which whitening occurs for intrinsic and extrinsic stains, and because peroxide appears in a "wide range of concentrations." *Id.* at 4. Reading the document as a whole, it is clear that the FDA believed it did not have sufficient information regarding peroxide-containing teeth whiteners to determine whether they should be regulated as OTC drugs, and thus declined to put forth any requirements in addition to those already applicable because of teeth whiteners' status as cosmetics. *See id.* ("In sum, there is insufficient data to determine whether, as a group, peroxide-containing tooth whitening preparations that act by chemical means to lighten tooth color meet the definition of a drug."). The denial does not, as Defendant claims, address the substance of any representations about the whitening effect of peroxide-containing products. In reply, Defendant argues that the denial "did not forbid intrinsic whitening claims for any product or concentration," (Doc. 37 at 6 (emphasis removed)), but fails to mention that the FDA did not "endeavor[] to regulate" representations about peroxide-containing whiteners at all. *In re PepsiCo, Inc.*, 588 F. Supp. 2d at 538 n.10. Its

[9] I take judicial notice of this FDA communication because it is an official record of the FDA, it is publicly available, and its accuracy cannot reasonably be questioned. *See Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59-60 (2d Cir. 2016).

rejection of the ADA's request is not "tantamount to a conscious decision" that representations such as those alleged here were "insufficiently misleading" to warrant regulation. *Bimont*, 2015 WL 5256988, at *6 (internal quotation marks omitted).

Defendant argues "that state law claims are preempted whenever they would add labeling restrictions or requirements beyond those in the FDCA, even where the FDA has not specifically addressed the label claims at issue." (D's Mem. 10 (citing *Bowling*, 65 F. Supp. 3d at 376).) In *Bowling*, the court addressed a mouthwash manufacturer's claims that its product containing sodium fluoride "restores enamel," and found that the FDCA preempted the plaintiff's state law claims alleging that that phrase was false and misleading. 65 F. Supp. 3d at 375-76. The court found that, pursuant to the final Anticaries Monograph that was "directly on point," *id.* at 376, "manufacturers of OTC drugs containing sodium fluoride are allowed (1) to represent that such drugs prevent tooth decay and (2) to provide further labeling to explain how decay is prevented," *id.* at 373. Thus, while the FDA may not have considered the exact language addressed in *Bowling*, it had clearly addressed the substance of the claims at issue. *See id.*; *In re PepsiCo, Inc.*, 588 F. Supp. 2d at 538; *see also O'Connor v. Henkel Corp.*, No. 14-CV-5547, 2015 WL 5922183, at *6 (E.D.N.Y. Sept. 21, 2015) (state law claims premised on misleading statement of cosmetic's net weight were preempted because the FDA regulates statements about net weight and imposes additional requirements in situations where generic net weight statement may be misleading, but "declined to do so for the category of products at issue here").

The *Bowling* court acknowledged that it may have come to a different conclusion "if the FDA had issued *no* guidance as to dental hygiene products." 65 F. Supp. 3d at 376 (emphasis in original).[10] But the *Bowling* court construed the relevant "subject matter that is being

[10] The *Bowling* court's full reasoning is as follows: "[I]f the FDA had issued *no* guidance as to dental hygiene products, [it would be] possible to conclude that [defendant's mouthwash] falls beyond the scope of federal

challenged," *In re PepsiCo, Inc.*, 588 F. Supp. 2d at 538, at too high a level of generality. The final Anticaries Monograph approves only certain claims regarding decay prevention in dental hygiene products with certain active ingredients for certain intended uses. That a toothpaste contains sodium fluoride, an active ingredient approved under the monograph, and therefore may advertise its cavity-preventing qualities, does not, for example, permit its manufacturer to make misleading claims about that toothpaste's ability to clear acne. If the quoted language in *Bowling* were taken literally and out of context, a manufacturer could make such a claim, and then point to the Anticaries Monograph to immunize it against state law claims challenging that assertion. Congress cannot have intended such sweeping preemption. *See id.* at 538-39 & n.10 (state law claims may "survive preemption where they are premised on misrepresentations concerning subject matter that the FDA has not endeavored to regulate").

Unlike *Bowling*, where the FDA had addressed the substance of the plaintiff's claims, Plaintiff here challenges Defendant's claims regarding a subject the FDA did not consider in its rulemaking: the whitening effect of hydrogen peroxide in toothpaste. *See* Anticaries Monograph, 60 Fed. Reg. at 52506 (listing which active ingredients were approved and which were considered but not approved). Nor has it otherwise purported to regulate what manufacturers of such products may or may not claim regarding whitening.

Defendant has thus not identified any federal requirements applicable to its Optic White products beyond the FDCA's general prohibition against false and misleading labeling. *See Dean*, 2015 WL 3999313, at *10 ("In short, the FDA has not issued regulations concerning the 'deep whitening' claims at issue here . . . ."). Because that general prohibition is identical to the

---

regulation entirely." *Id.* As discussed above, however, even if there were no monograph directly related to the Optic White products, they would still be subject to federal law requiring that their labeling and packaging not be false or misleading. *See* 21 U.S.C. §§ 331(a), 352(a)(1), 362(a).

requirement Plaintiff seeks to impose through her claims under state law, those claims are not expressly preempted. *See Reid*, 2016 WL 403497, at *10 (claims based on state law prohibiting false or misleading labeling of drugs are not preempted because they "are identical to the provisions of the FDCA").

C. Primary Jurisdiction Doctrine

Even if Plaintiff's claims are not preempted, Defendant argues that they should be stayed or dismissed under the primary jurisdiction doctrine, given that the FTC is currently investigating the issue of which Plaintiff complains. (D's Mem. 8, 13.) "The doctrine of primary jurisdiction is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties. The doctrine's central aim is to allocate initial decisionmaking responsibility between courts and agencies and to ensure that they do not work at cross-purposes." *Ellis v. Tribune Television Co.*, 443 F.3d 71, 81 (2d Cir. 2006) (citation and internal quotation marks omitted). It dictates that "whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body," the court should defer decision to that agency. *Id.* (internal quotation marks omitted).

Despite its name, the doctrine is not jurisdictional, *see Balt. & Ohio Chi. Terminal R.R. Co. v. Wis. Cent. Ltd.*, 154 F.3d 404, 411 (7th Cir. 1998) (the doctrine "presupposes that the court . . . has jurisdiction"); *P.R. Tel. Co. v. WorldNet Telecomm., Inc.*, 52 F. Supp. 3d 370, 377 (D.P.R. 2014) ("It is well-settled that the doctrine of primary jurisdiction is not, despite its name, jurisdictional.") (internal quotation marks omitted), and "'[e]ven when primary jurisdiction is not

statutorily required . . . courts may still apply the doctrine as a prudential matter,'" *Reid*, 2016 WL 403497, at *11 (quoting *Ellis*, 443 F.3d at 82-83) (alteration in original).[11]

> In assessing whether to defer decision to an agency, courts should consider four factors: (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made. We have noted as well that the court must also balance the advantages of applying the doctrine against the potential costs resulting from complications and delay in the administrative proceedings."

Ellis, 443 F.3d at 82-83 (citation, alteration, and internal quotation marks omitted). "Common sense tells us that even when agency expertise would be helpful, a court should not invoke primary jurisdiction when the agency is aware of but has expressed no interest in the subject matter of the litigation. Similarly, primary jurisdiction is not required when a referral to the agency would significantly postpone a ruling that a court is otherwise competent to make." *Astania v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 761 (9th Cir. 2015).

1. FTC's Expertise

The first factor requires consideration of whether Plaintiff's claims present issues that are "within the conventional experience of judges" or "involve technical or policy considerations

[11] Although Defendant contends that its primary jurisdiction argument should be analyzed as a motion to dismiss for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), (D's Mem. 7), the "doctrine is specifically applicable to claims *properly cognizable in court* that contain some issue within the special competence of an administrative agency," *Nw. Airlines, Inc. v. Cty. of Kent, Mich.*, 510 U.S. 355, 366 n.10 (1994) (emphasis added) (internal quotation marks omitted). While it thus appears such an argument is properly analyzed under Rule 12(b)(6), *see Reid*, 2016 WL 403497, at *11 (analyzing primary jurisdiction argument under Rule 12(b)(6)); *Keeling v. Esurance Ins. Co.*, No. 10-CV-835, 2012 WL 699580, at *5-6 (S.D. Ill. Mar. 1, 2012) (same); *see also Goldemberg v. Johnson & Johnson Consumer Cos., Inc.*, 8 F. Supp. 3d 467, 476 (S.D.N.Y. 2014) ("Rule 12(b)(1) concerning lack of subject matter jurisdiction is inapplicable" to application of primary jurisdiction doctrine), I find the discussion sufficiently akin to a motion under Rule 12(b)(1) – in connection with which matters outside the pleadings are properly considered, *Morrison v. Nat'l Austl. Bank, Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008), *aff'd*, 561 U.S. 247 (2010) – so that consideration of documents beyond the four corners of the complaint is appropriate, *see Sierra Club v. Chesapeake Operating, LLC*, No. 16-CV-134, 2017 WL 1287546, at *2 (W.D. Okla. Apr. 4, 2017) (on motion to dismiss on abstention and primary jurisdiction grounds, court may consider documents outside the pleadings). In any event, the parties have agreed that I may consider recent correspondence between Defendant and the FTC "only to show that such correspondence exists and not for its content." (Doc. 45.)

within the agency's field of expertise." *Ellis*, 443 F.3d at 82-83. The issue in this case – namely, whether Defendant's claims that its Optic White products deeply whiten and whiten beyond surface stains are false or misleading – "fall within the conventional experience of judges." *Reid*, 2016 WL 403497, at *11; *see Dean*, 2015 WL 3999313, at *4 ("District courts handle similar claims [regarding misleading advertising] all the time, and have not faltered for lack of specific agency guidance."); *Elkind*, 2015 WL 2344134, at *10 (courts are "well-equipped" to evaluate claims of deceptive advertising); *cf. Ault v. J.M. Smucker Co.*, No. 13-CV-3409, 2014 WL 1998235, at *5 (S.D.N.Y. May 15, 2014) ("While the Court would welcome the FDA's guidance on the definition of 'natural,' this case is far less about science than it is about whether a label is misleading.") (internal quotation marks omitted). On the other hand, the Court is presumably less well-equipped than the FTC to determine as a matter of science "whether certain claims about the whitening capabilities of Optic White toothpaste are valid and supported," (D's Mem. 13), and what sort of labeling would fairly represent those capabilities or lack thereof. This factor is thus neutral.

2. FTC's Discretion

The FTC has broad power to prevent manufacturers "from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practice in or affecting commerce." 15 U.S.C. § 45(a)(2). And "[t]he FTC is specifically tasked with addressing deceptive labeling." *Belfiore v. Proctor & Gamble Co.*, 311 F.R.D. 29, 78 (E.D.N.Y. 2015). This second factor weighs in favor of deferring decision to the FTC. *See Reid*, 2016 WL 403497, at *12; *Elkind*, 2015 WL 2344134, at *10.

3. Risk of Inconsistent Rulings

Defendant is correct that because "the FTC is currently in the process of reviewing the validity of the exact claims at issue in this litigation," the risk that it would be subjected to inconsistent rulings is "particularly high." (D's Mem. 14.) *See Ellis*, 443 F.3d at 88 ("Courts should be especially solicitous in deferring to agencies that are simultaneously contemplating the same issues."). "Because [the FTC] is currently conducting an investigation into the lawfulness of the practice under attack, [action by this Court] would invite the very disruption that the doctrine is meant to discourage." *Ellis*, 443 F.3d at 88 (alteration, omission, and internal quotation marks omitted). Thus this factor weighs in favor of deferring decision to the FTC.

4. Prior Application to the FTC

This factor also favors deferring decision to the FTC, given its ongoing investigation as to whether the claims at issue are supported. *See Dean*, 2015 WL 3999313, at *6 ("Defendant's argument is certainly made stronger by the fact that the FTC has already launched an investigation.").

After consideration of the four factors, I find it appropriate to allow the FTC to address the issues raised here in the first instance. Further, given the FTC's pending investigation into the very claims at the heart of Plaintiff's case (which inquiry remains active into 2017, (*see* Doc. 39 Ex. 17)), the advantages of application of the doctrine, in light of the agency's expertise, *see Ellis*, 443 F.3d at 90, and the progress it has made, outweigh the potential for undue delay. While invoking the primary jurisdiction of the FTC may theoretically delay resolution of Plaintiff's claims, the prospect of significant delay is reduced by the fact that the FTC has

already been investigating this matter for more than two years, *see Dean*, 2015 WL 3999313, at *6,[12] while this case is barely off the ground.

5. Whether Dismissal Is Appropriate

"Once a district court determines that primary jurisdiction is appropriate, it may either stay proceedings or dismiss the case without prejudice." *Astania*, 783 F.3d at 761. "In doing so, the court must take care that its deferral not unfairly disadvantage either party. The paramount concern is that the deferral not work a time-bar to claims that will in all likelihood be refiled in federal court after the agency acts." *Johnson v. Nyack Hosp.*, 86 F.3d 8, 11 (2d Cir. 1996) (citation omitted). As the Second Circuit has not decided whether equitable tolling applies to claims that have been dismissed pursuant to the primary jurisdiction doctrine, *see id.* at 11-12; *Meau v. Sentry Cas. Co.*, No. 15-CV-67, 2016 WL 4491626, at *6 (D. Vt. Aug. 25, 2016), I find that a stay is appropriate here to protect Plaintiff should she wish to pursue the matter following the FTC's action, *see Meau*, 2016 WL 4491626, at *6 (stay is preferable because "it avoids any potential issues about the statute of limitations and whether equitable tolling might be available").

[12] The court in *Dean* did not ultimately dismiss pursuant to the primary jurisdiction doctrine because Defendant "ha[d] not provided any specifics about [the FTC] investigation." *Id.* at *6. Defendant has cured that problem here by providing information regarding the extent and continuing nature of the FTC's investigation.

III. CONCLUSION

For the reasons stated above, Defendant's motion to dismiss the case is DENIED. This case is STAYED until the conclusion of the FTC's investigation. Defendant is to provide status updates every six months (and promptly upon the conclusion of the FTC inquiry). The Clerk of Court is directed to terminate the pending motion. (Doc. 26.)

SO ORDERED.

Dated: June 23, 2017
White Plains, New York

Cathy Seibel

CATHY SEIBEL, U.S.D.J.